DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

4426. Misbranding of suprarenal concentrate capsules and yellow bone marrow concentrate. U. S. v. 213 Bottles, etc. (F. D. C. No. 36512. Sample Nos. 37528–L, 37529–L.)

LIBEL FILED: April 20, 1954, District of New Jersey.

ALLEGED SHIPMENT: On or about December 2, 1953, and January 20 and February 16, 1954, by the Armour Laboratories, from Bradley, Ill.

PRODUCT: 213 bottles of *suprarenal concentrate capsules* and 90 bottles of *yellow bone marrow concentrate* at East Paterson, N. J.

LABEL, IN PART: (Bottle) "100—2 Grain Suprarenal Concentrate Capsules Each Capsule Contains The Powdered Concentrate Derived From 15 Grains Of Fresh Suprarenal Glands Relatively Free From Epinephrine. The Armour Laboratories * * * Chicago 11, Ill." and "Armour Laboratories 100 Glanules Y. B. M. Yellow Bone Marrow Concentrate * * * Indications: Mild Chronic Agranulocytosis Due To Infection Or The Toxic Action Of Drugs * * * Each Glanule Contains 21 Milligrams of Nonsaponifiable Material Derived From 12.5 Grams Of Fresh Yellow Bone Marrow."

NATURE OF CHARGE: *Yellow bone marrow concentrate.* Misbranding, Section 502 (a), certain statements on the bottle label and in a brochure attached to each bottle of the article were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for chronic agranulocytosis and leukopenia. The article was not an adequate and effective treatment for such conditions.

Suprarenal concentrate capsules. Misbranding, Section 503 (b) (4), the article was a drug to which Section 503 (b) (1) did not apply, and its label bore the statement "Caution: Federal law prohibits dispensing without prescription."

Further misbranding, Section 502 (f) (1), the labeling of the *yellow bone marrow concentrate* and the *suprarenal concentrate capsules* failed to bear adequate directions for use, and these articles were not entitled to any exemption from such requirement.

DISPOSITION: June 2, 1954. Default decree of condemnation and destruction.

4427. Misbranding of Mona-Serts vaginal tablets. U. S. v. 1,992 Boxes * * *. (F. D. C. No. 36812. Sample No. 86230–L.)

LIBEL FILED: May 28, 1954, Western District of Kentucky.

ALLEGED SHIPMENT: On or about June 1, 1952, by Strong, Cobb & Co., Inc., from Cleveland, Ohio.

PRODUCT: 1,992 boxes of *Mona-Serts vaginal tablets* at Louisville, Ky., in possession of the Wintersmith Chemical Co., Inc. A leaflet entitled "Mona-Serts Vaginal Tablets" was enclosed in each box.

RESULTS OF INVESTIGATION: In addition to the leaflet enclosed in each box, a number of leaflets entitled "Mona-Serts Vaginal Tablets Antiseptic—Fungicidal" had been printed locally for the consignee and were in his possession.

LABEL, IN PART: (Box) "24 Tablets Mona-Serts Vaginal Tablets Antiseptic—Fungicidal For the treatment of vaginal infections Each tablet contains: Aluminum Caprylate. . . . 3 grs. Phenylmercuric Acetate. . . . 0.3 mg. Urea. . . . 1.0 gr. In combination with Citric Acid, Boric Acid, Lactose and Dextrose."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the box label of the article and in the leaflet enclosed in each box were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for irritations of the vaginal tract, vaginal discharge, burning, chafing, and pruritis, and that it would restore normal physiological function of the vagina and re-establish the normal acidity of the vaginal tract. The article was not an adequate and effective treatment for such conditions and would not fulfill the promises of benefit stated and implied. Further misbranding, Section 503 (b) (4), the article was a drug to which Section 503 (b) (1) applied, and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription." The article was misbranded in the above respects when introduced into and while in interstate commerce.

Further misbranding, Section 502 (a), certain statements in the leaflet entitled "Mona-Serts Vaginal Tablets Antiseptic—Fungicidal" accompanying the article were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for irritations of the vaginal tract, trichomonas vaginalis vaginitis, mycotic (monilia) vaginitis, and mixed infection vaginitis, and that it would restore normal physiological function of the vagina and re-establish the normal acidity of the vaginal tract. The article was not an adequate and effective treatment for such conditions and would not fulfill the promises of benefit stated and implied. The article was misbranded in such respect while held for sale after shipment in interstate commerce.

DISPOSITION: July 9, 1954. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

4428. Misbranding of William's Yukol. U. S. v. 22 Bottles, etc. (F. D. C. No. 36517. Sample No. 84852–L.)

LIBEL FILED: April 21, 1954, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about December 15, 1953, and February 3 and March 19, 1954, from New York, N. Y.

PRODUCT: 22 2-ounce bottles, 52 4-ounce bottles, and 57 8-ounce bottles of *William's Yukol* at Philadelphia, Pa.

RESULTS OF INVESTIGATION: The product, after shipment in interstate commerce, was promoted for sale on the premises of a local Philadelphia store through spiels given by Mrs. Mitze Fanelli, who represented the product for various conditions. In addition to the sales talk, there were displayed on the sales counter 3 letters, each mounted separately on a square of cardboard, containing claims and representations for the product.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended, namely, in the treatment of headaches, migraine headaches, coughs, rheumatism, lumbago, neuritis, arthritis, backache, sinus trouble, fibrositis, myositis, and pain in the feet and legs, which were the conditions and purposes for which the article was offered to the public. The article was misbranded while held for sale after shipment in interstate commerce.

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*See also Nos. 4423, 4426.